Vitamin E Stabilization of Radiation Cross-linked UHMWPE by Diffusion

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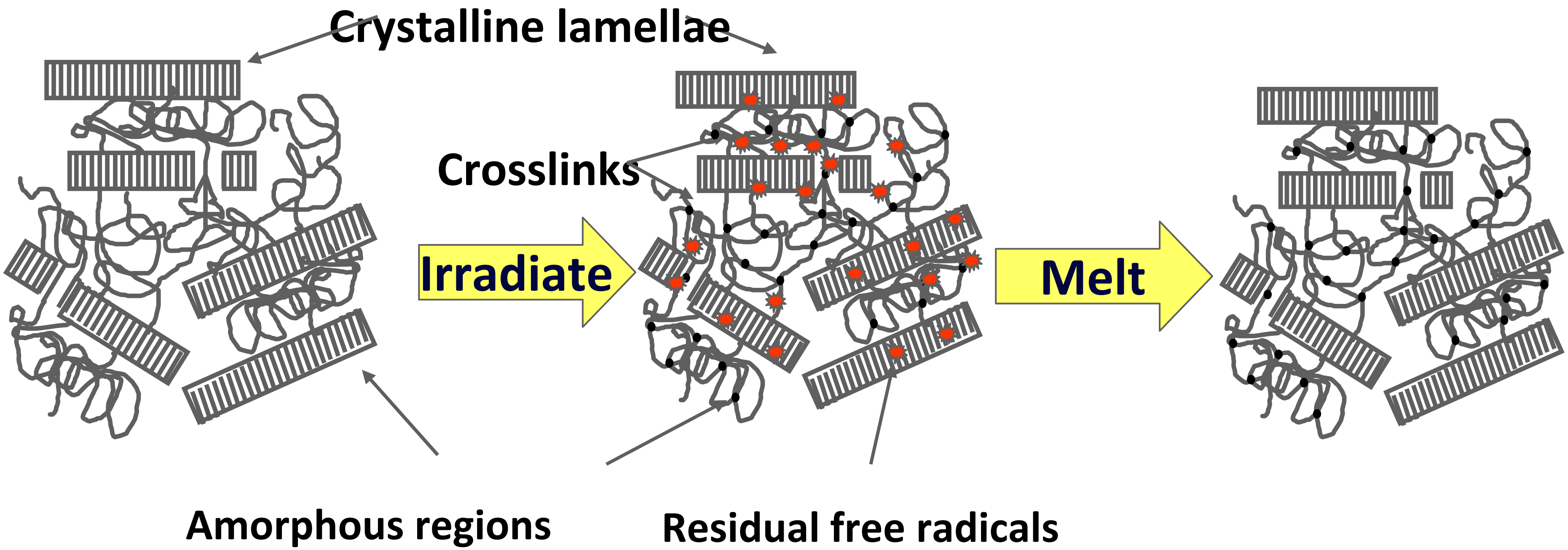
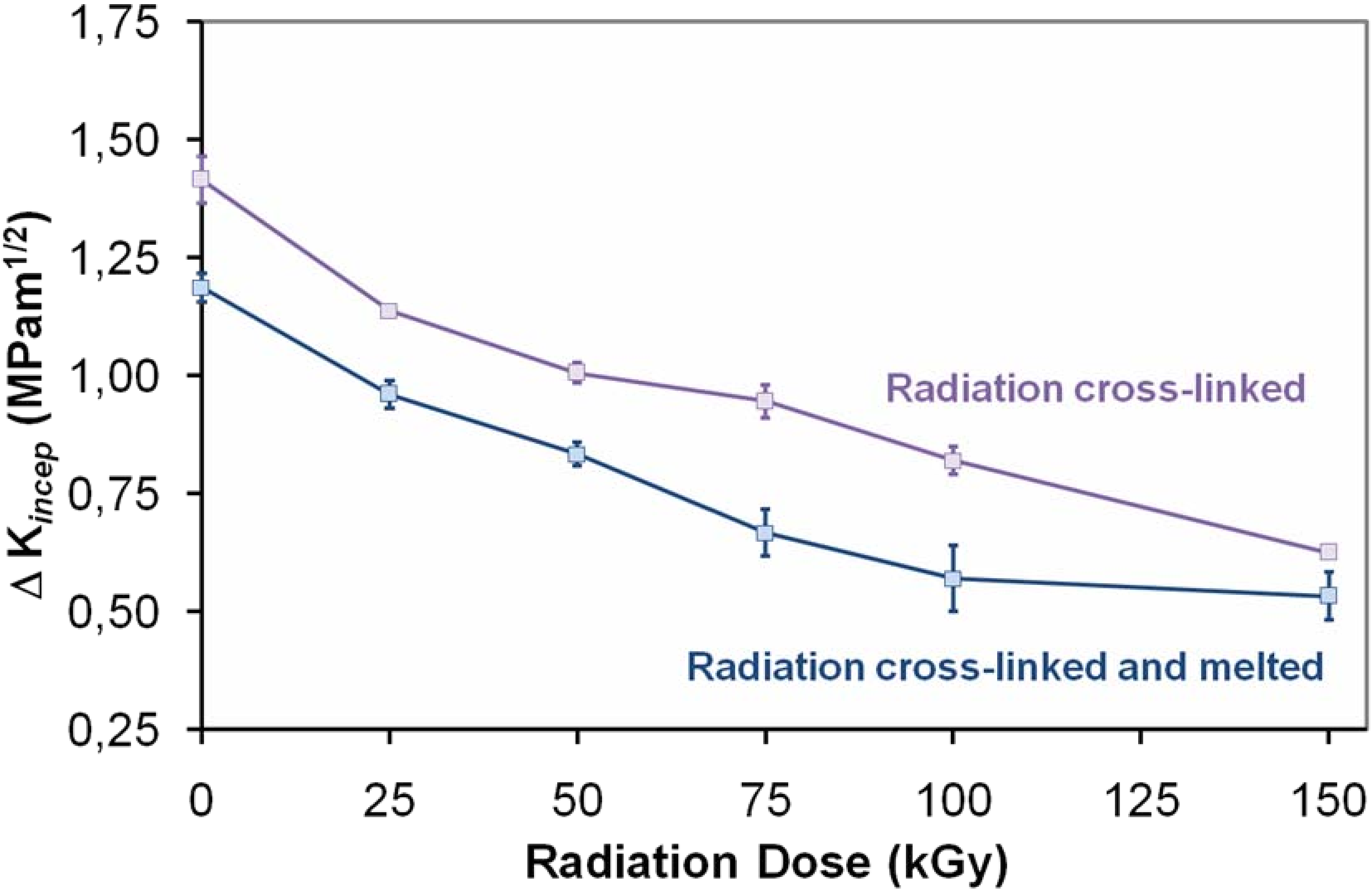
Mechanisms of mechanical property loss in radiation cross-linked and melted UHMWPE



Fatigue strength decrease in cross-linked and UHMWPE



Oral et al. Mechanisms of decrease in fatigue crack propagation resistance in irradiated and melted UHMWPE Biomaterials 27: 917-925 (2006)

Mechanisms of mechanical property loss in radiation cross-linked and melted UHMWPE

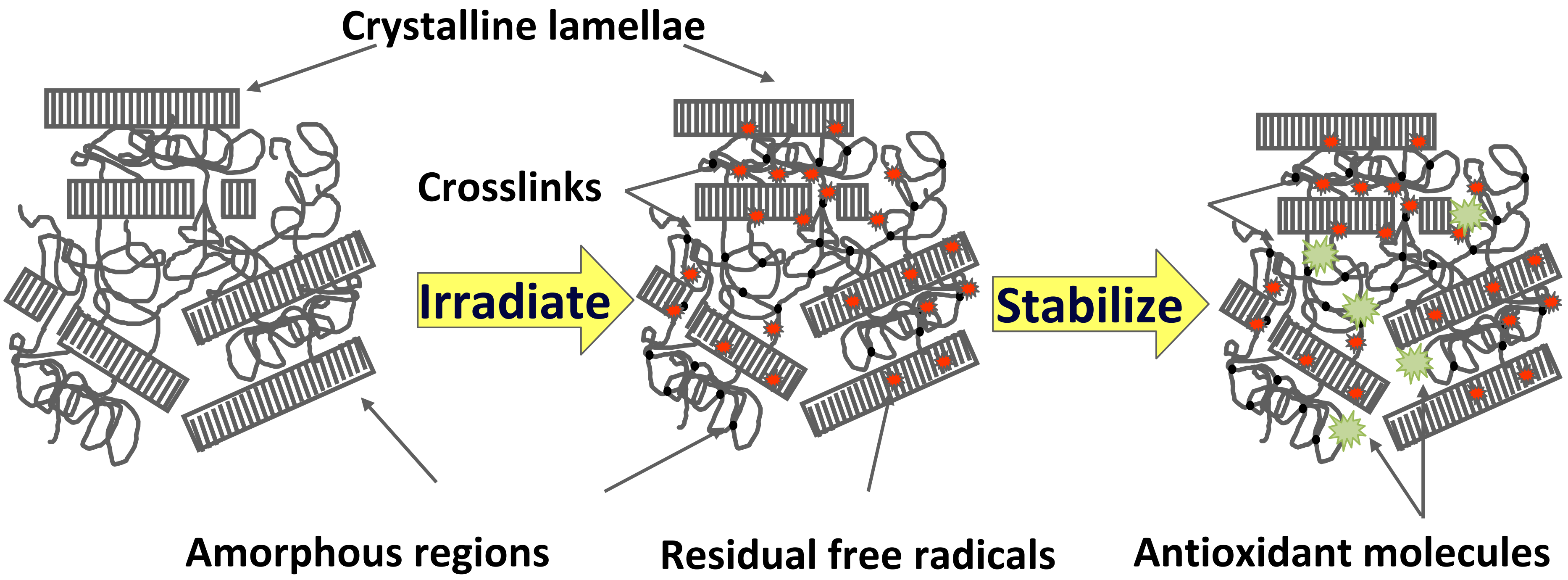
	Crystallinity (%)	Elongation-to-break (%)
Unirradiated	63±2	481±40
100-kGy irradiated	69±1	214±7
100-kGy irradiated and melted	58±1	233±16

→ Reduction in plasticity during cross-linking

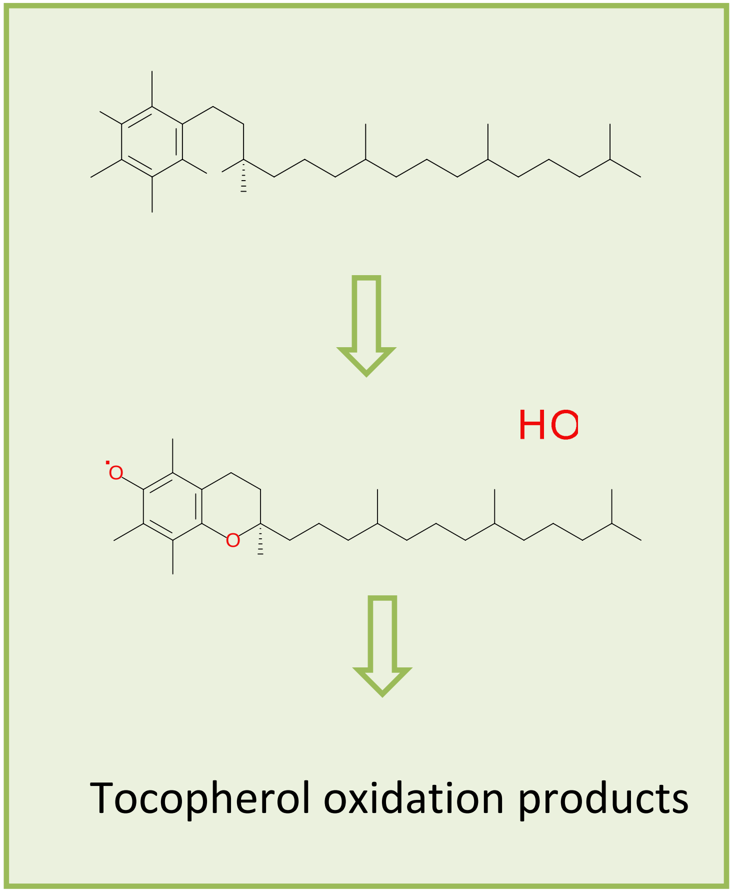
→ Reduction in crystallinity during post-irradiation melting

Antioxidant Stabilization of UHMWPE

Goal: To stabilize against free radicals without post-irradiation melting and the associated mechanical property loss



Vitamin E
(Chain breaking antioxidant)



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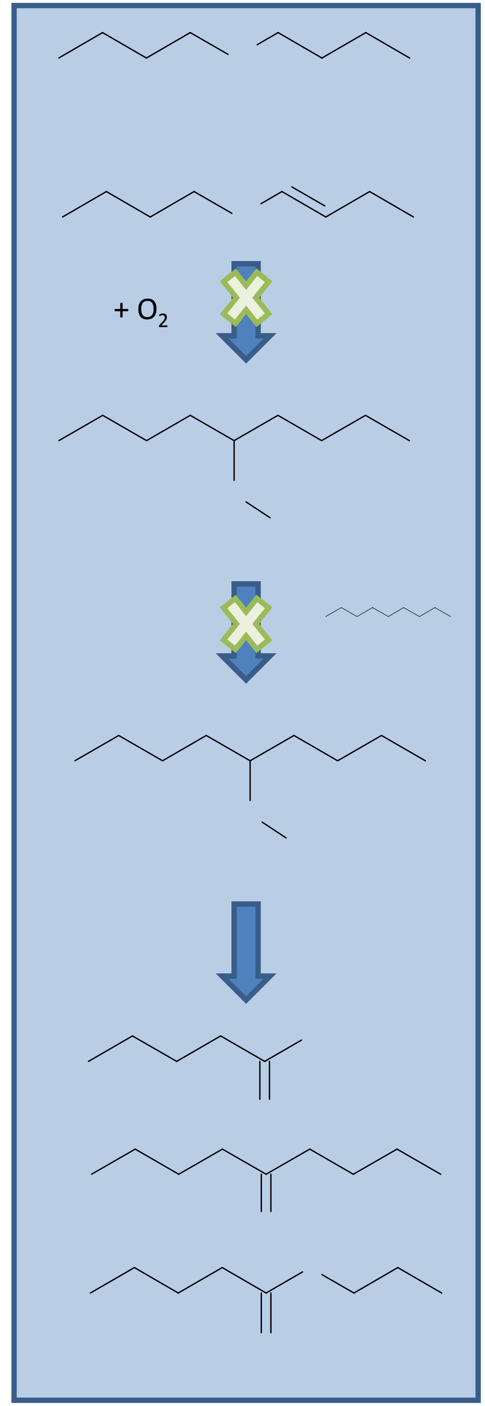


Alternative Vitamin E Incorporation Methods

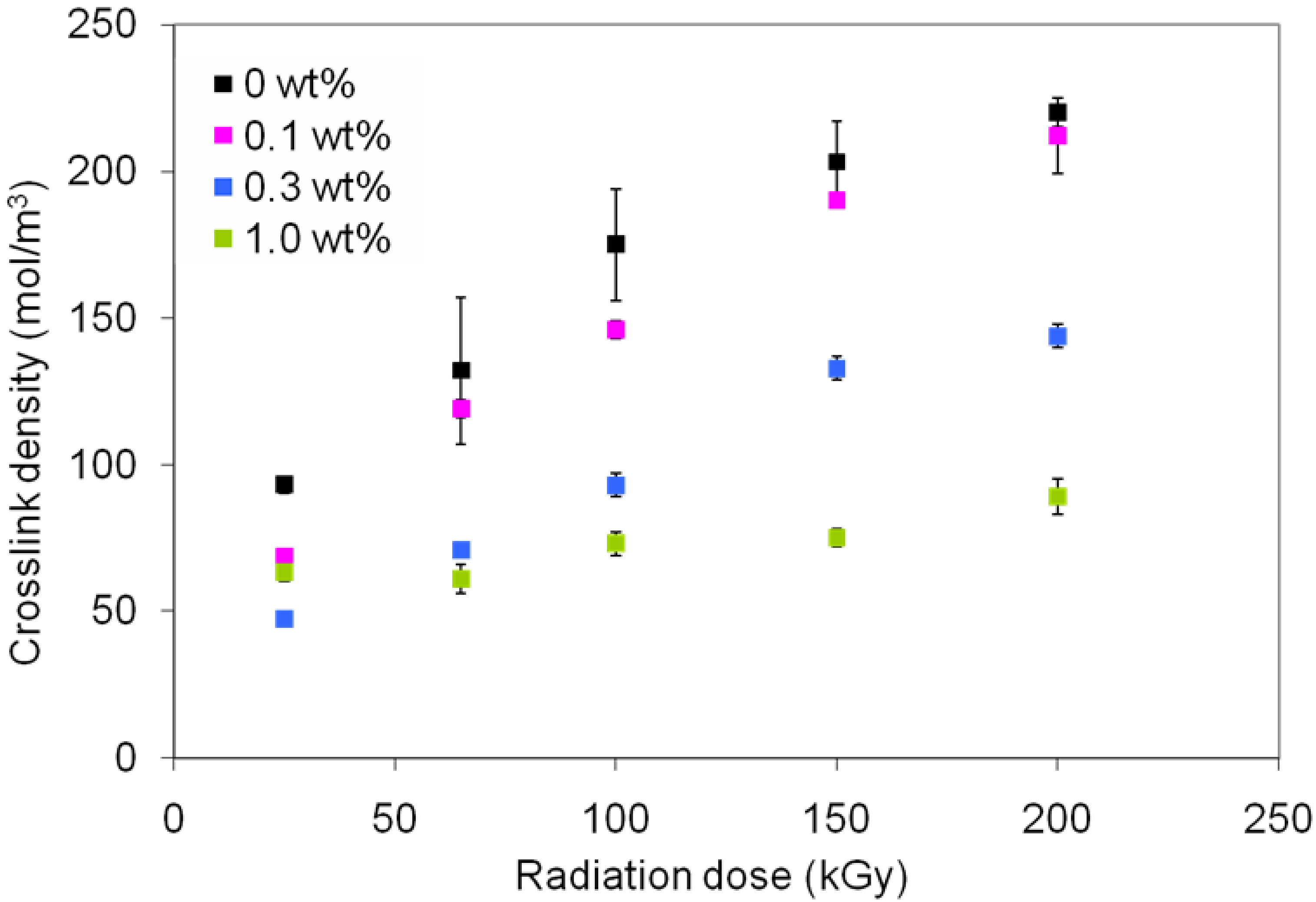
Pre-consolidation Blending

Blending → Consolidation → Irradiation

Post-irradiation Diffusion

Consolidation → Irradiation → Diffusion → Irradiation

Cross-link density saturation in cross-linked UHMWPE



Oral et al. Characterization of irradiated blends of alpha-tocopherol and UHMWPE. Biomaterials 26: 6657-6663 (2005)

Oral et al. The effects of high dose irradiation on the crosslinking of vitamin E-blended UHMWPE. Biomaterials 29: 3557-3560 (2008)

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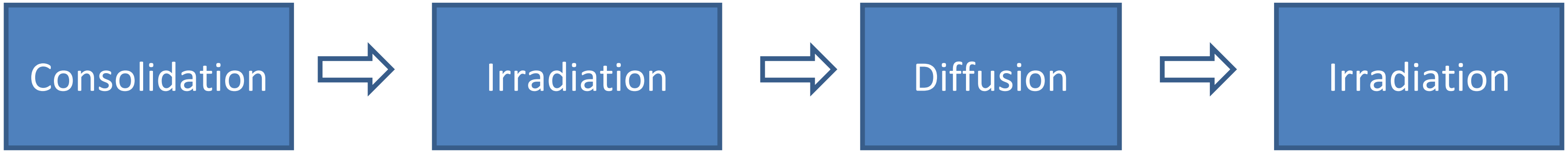

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Biomaterials 25 (2004) 5515–5522

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α-Tocopherol-doped irradiated UHMWPE for high fatigue resistance and low wear

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Diffusion of vitamin E in ultra-high molecular weight polyethylene

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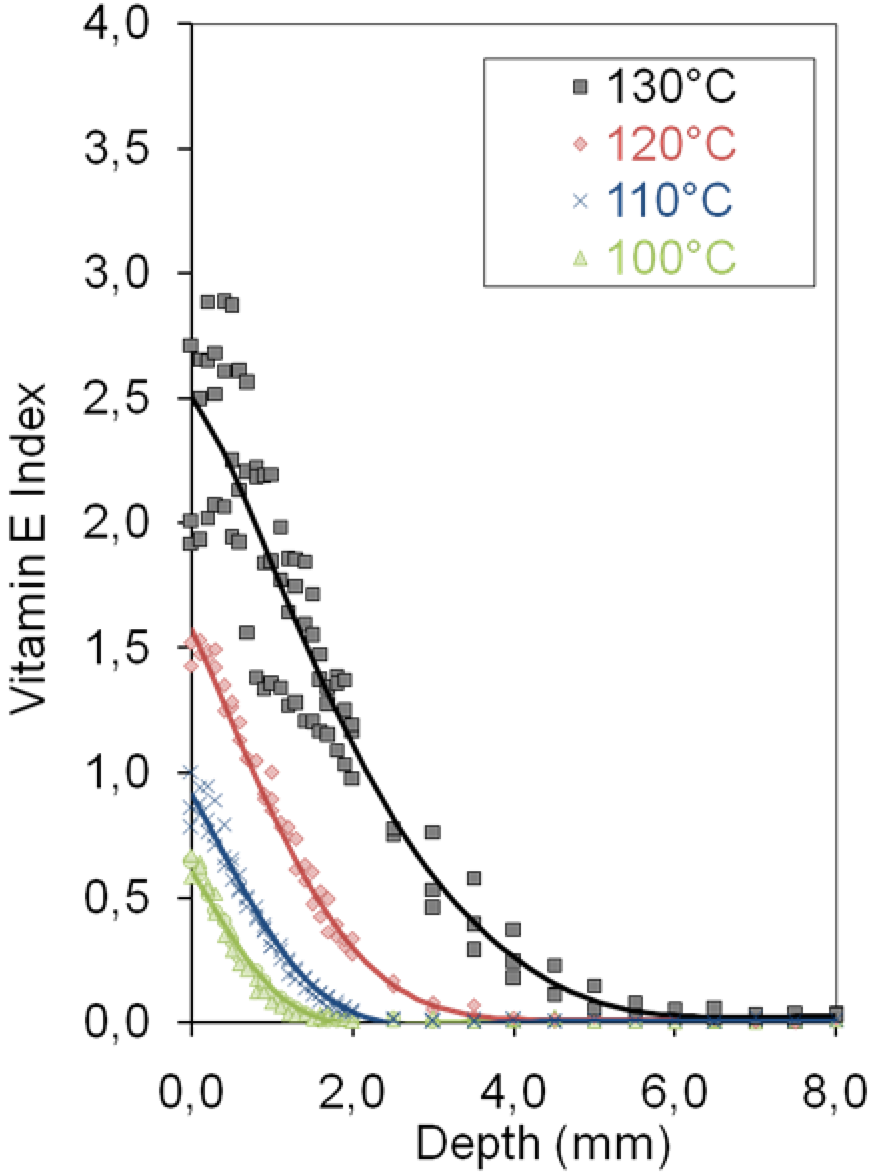
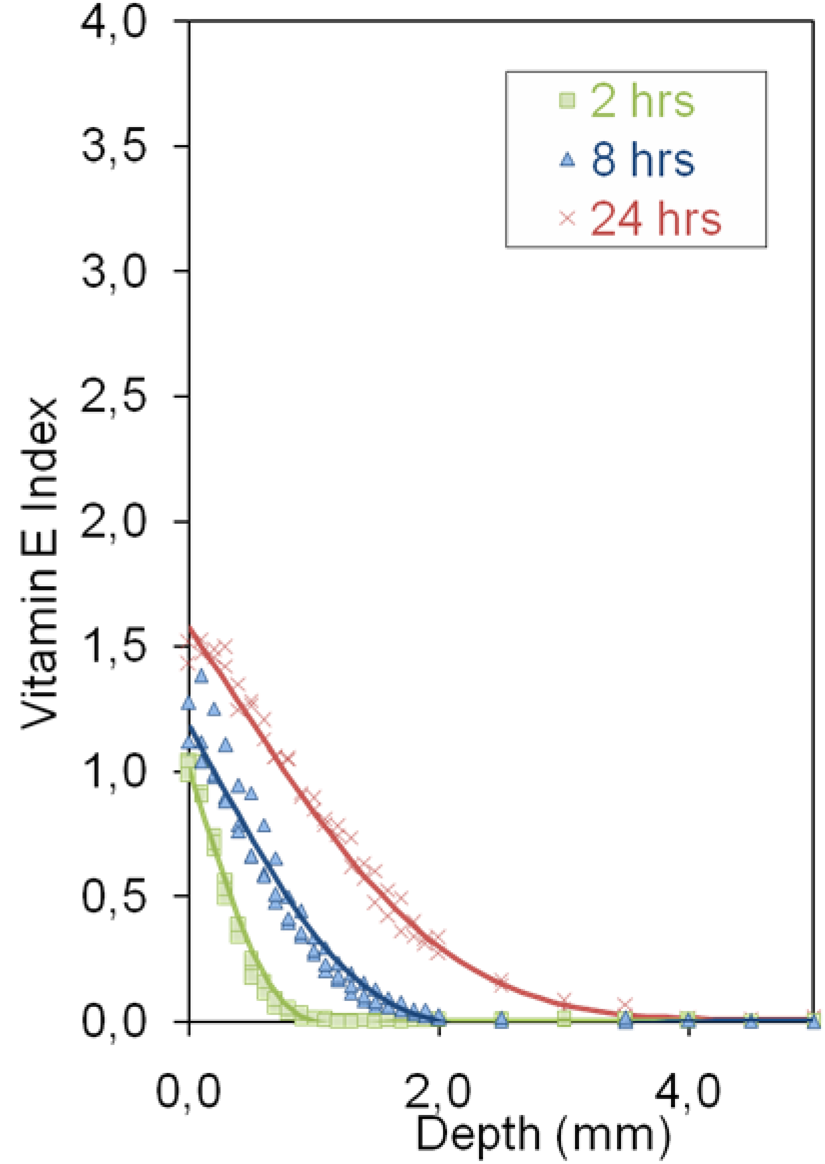
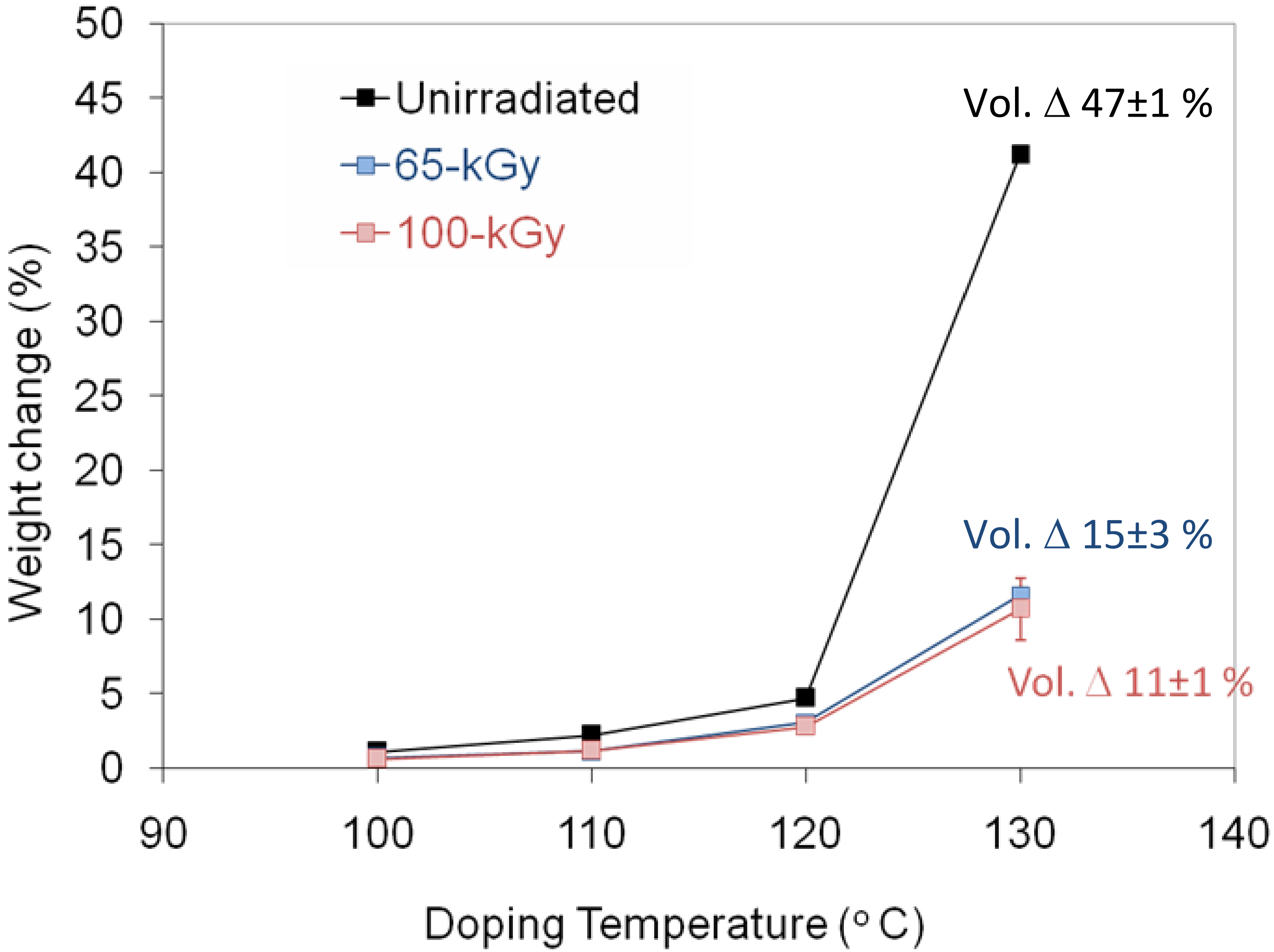
Effect of temperature on diffusion (24 hours)



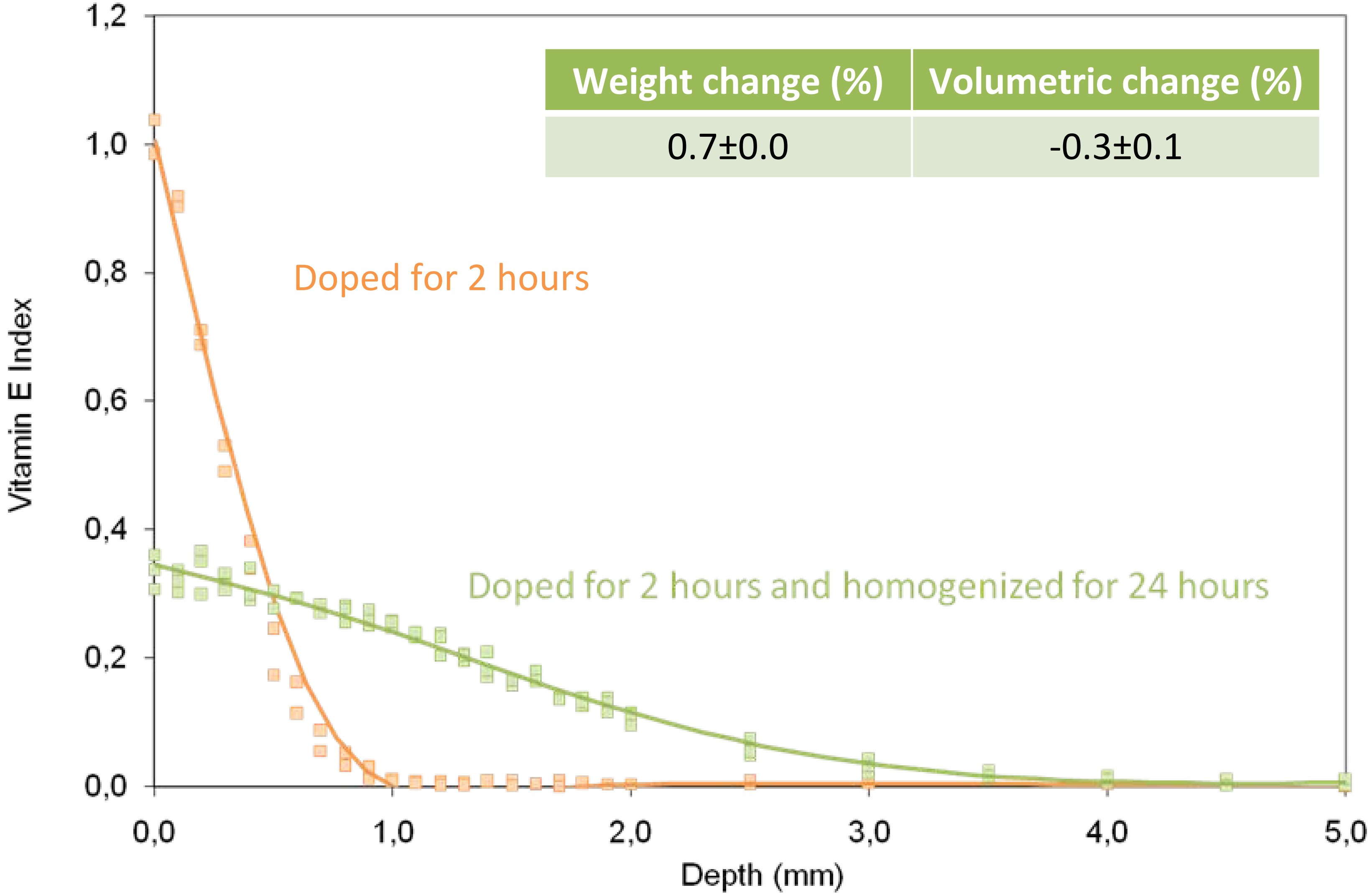
Effect of time on diffusion (120°C)



Diffusion into finished components



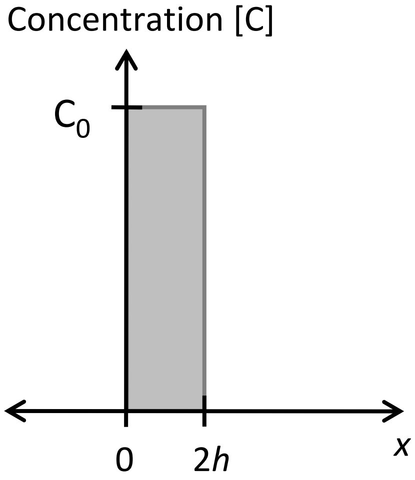
Diffusion and Homogenization



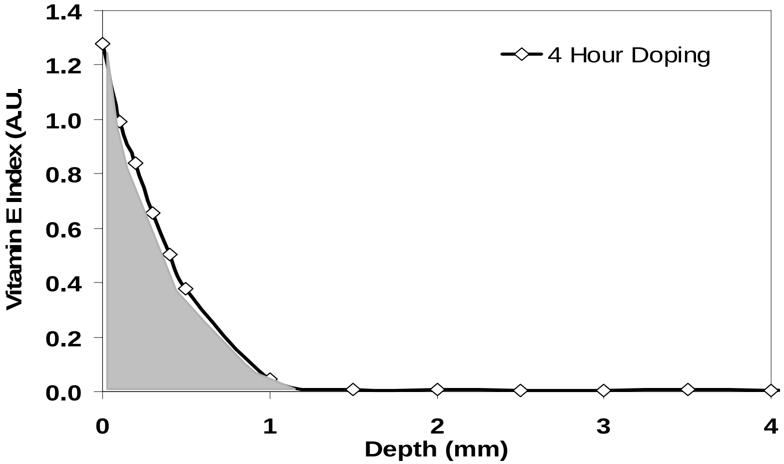
Analytical Model of Homogenization

$$C(x,t)=\left(\frac{C_0}{2}\right)\left[erf\left(\frac{h-x}{2\sqrt{Dt}}\right)+erf\left(\frac{h+x}{2\sqrt{Dt}}\right)\right] \Rightarrow C(x,t)=\left(C_0\right)\left[erf\left(\frac{h-x}{2\sqrt{Dt}}\right)+erf\left(\frac{h+x}{2\sqrt{Dt}}\right)\right]$$

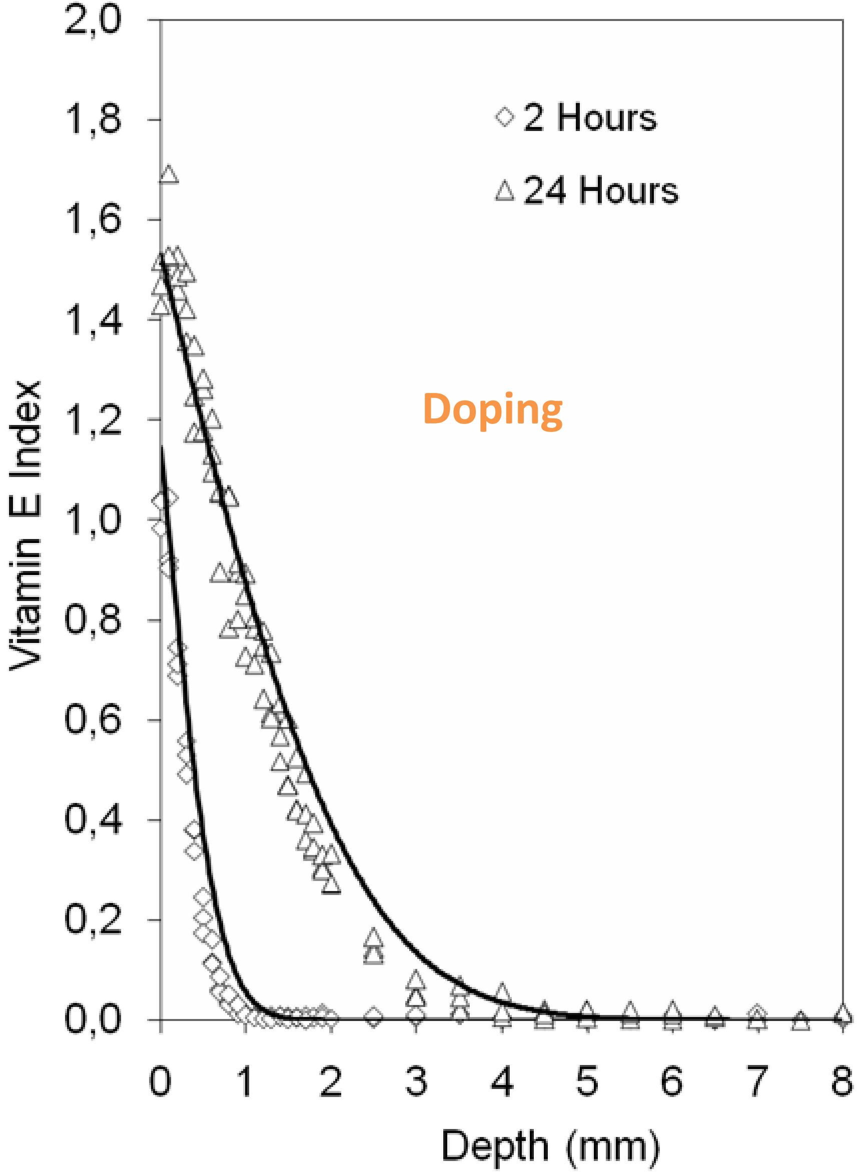
<u>Idealized</u>

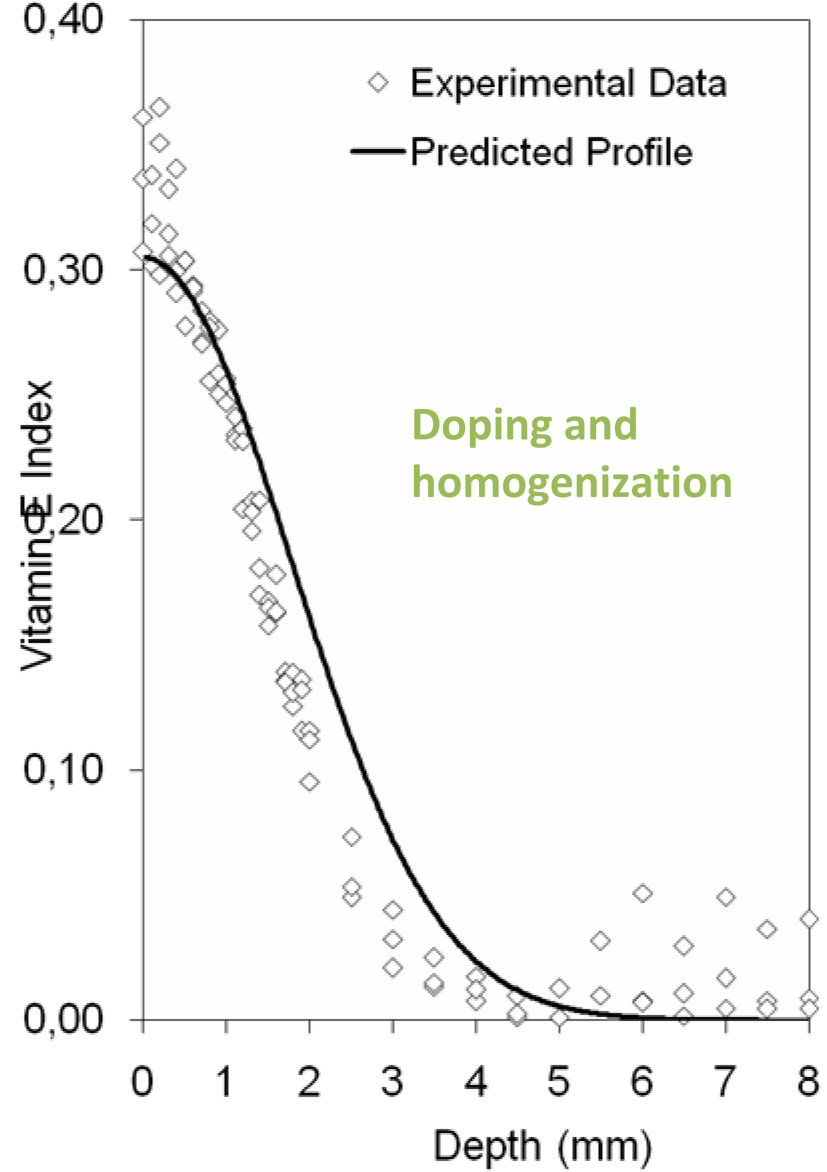


<u>Actual</u>



Analytical Model of Homogenization



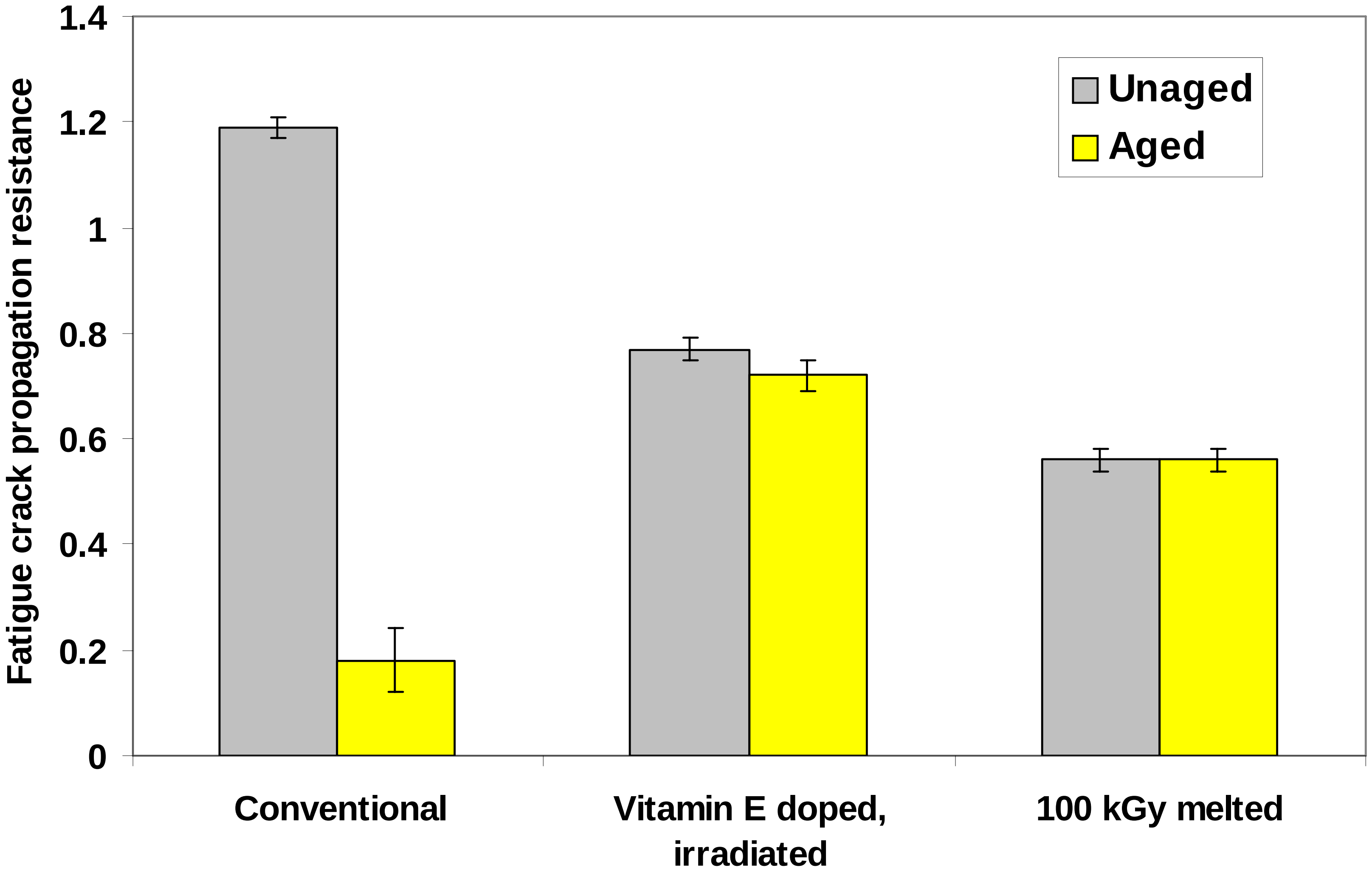


$\chi^2 \approx 0.8$

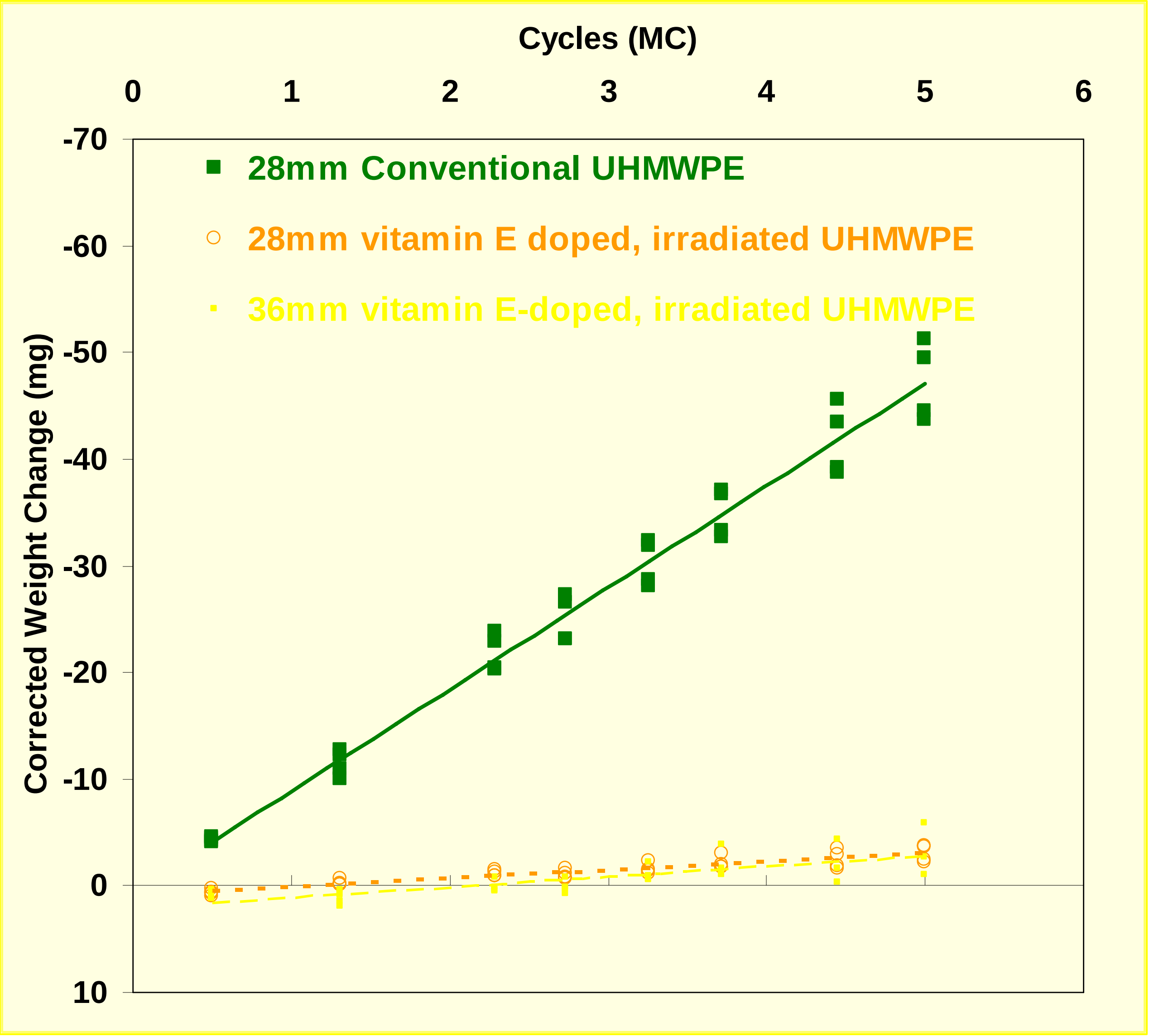
Mechanical Properties

	Gamma Sterilized UHMWPE	85-kGy vitamin E doped, homogenized and gamma sterilized	100 kGy Melted*
UTS (MPa)	52±5	46±3	33±3
e_b (%)	347±35	230±9	245±10
Crystallinity (%)	68±2	71±2	59±2

Fatigue Properties



Hip Wear



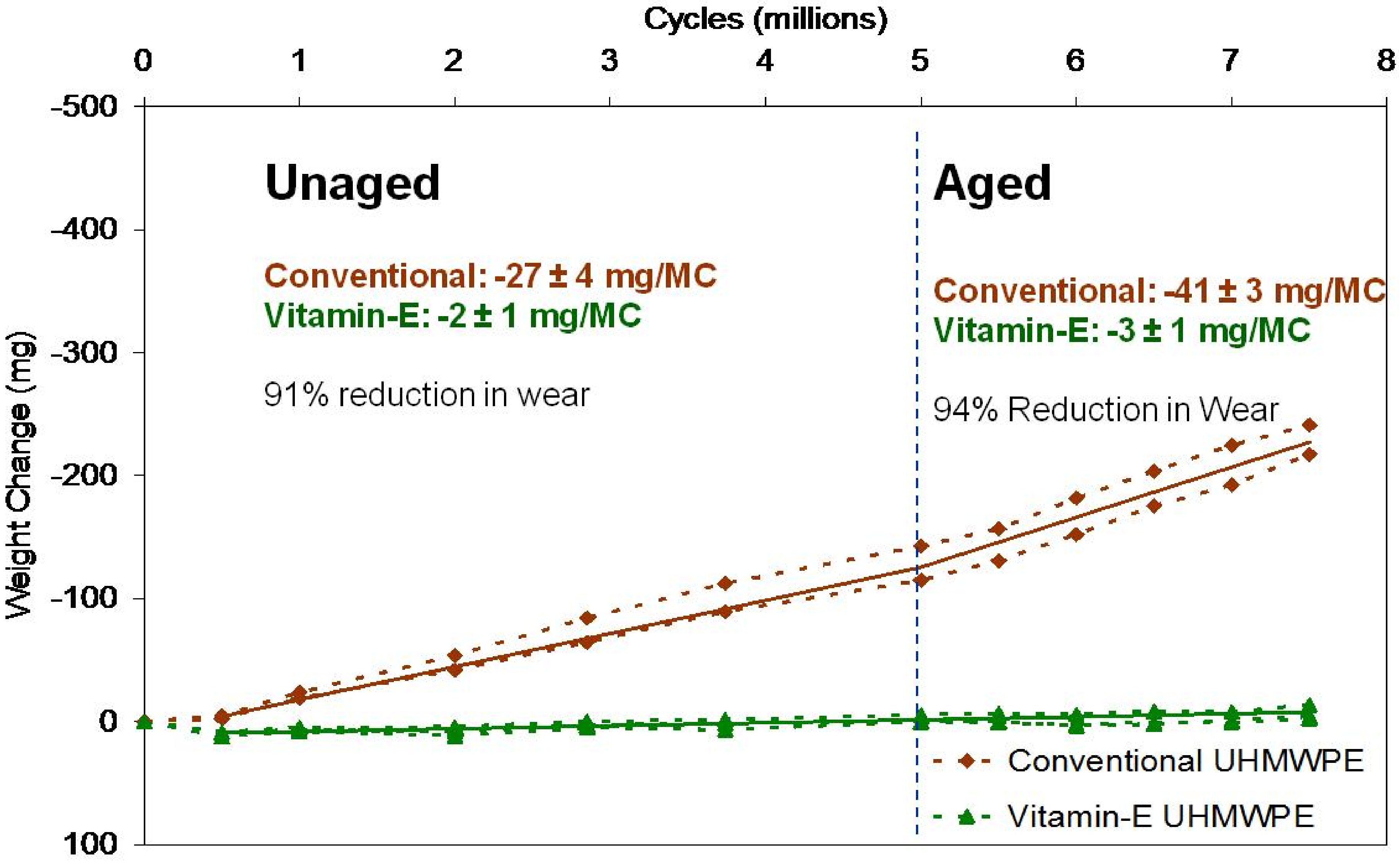
10±1 mg/MC

1±1 mg/MC

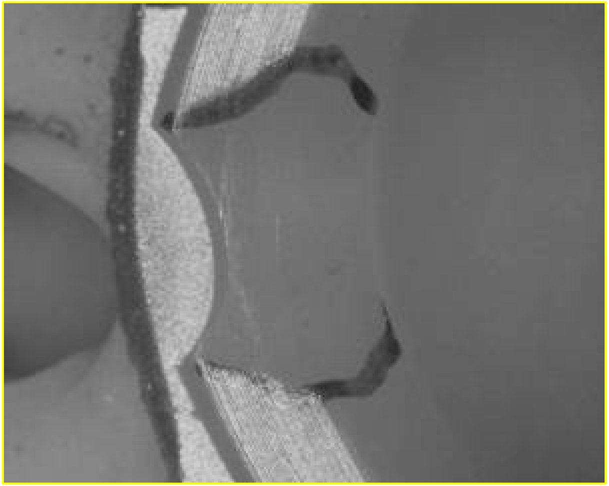
1±2 mg/MC

Oral et al. Wear resistance and mechanical properties of highly crosslinked UHMWPE doped with vitamin E. Journal of Arthroplasty 21: 580-591 (2006)

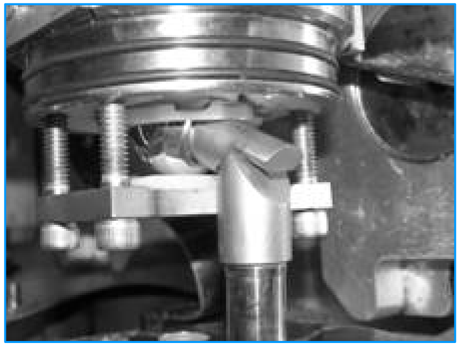
Knee Wear

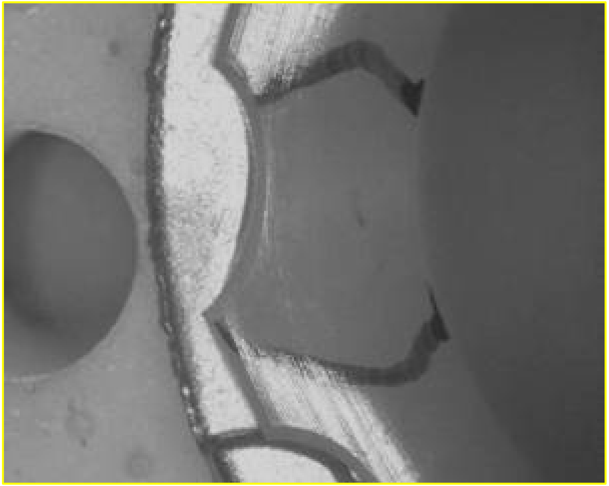

Cycles (millions)
0
1
2
3
4
5
6
7
8
-500
-400
-300
-200
-100
0
100
Weight Change (mg)
Unaged
Conventional: -27 ± 4 mg/MC
Vitamin-E: -2 ± 1 mg/MC
91% reduction in wear
Aged
Conventional: -41 ± 3 mg/MC
Vitamin-E: -3 ± 1 mg/MC
94% Reduction in Wear
Conventional UHMWPE
Vitamin-E UHMWPE

Rim Impingement Fatigue Resistance

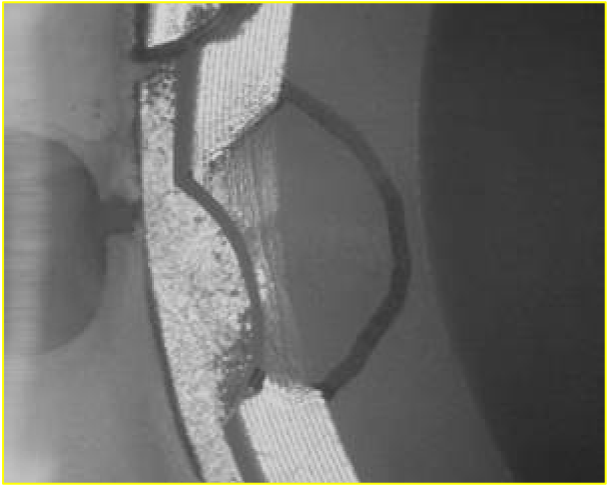


Conventional gamma sterilized UHMWPE 28 mm



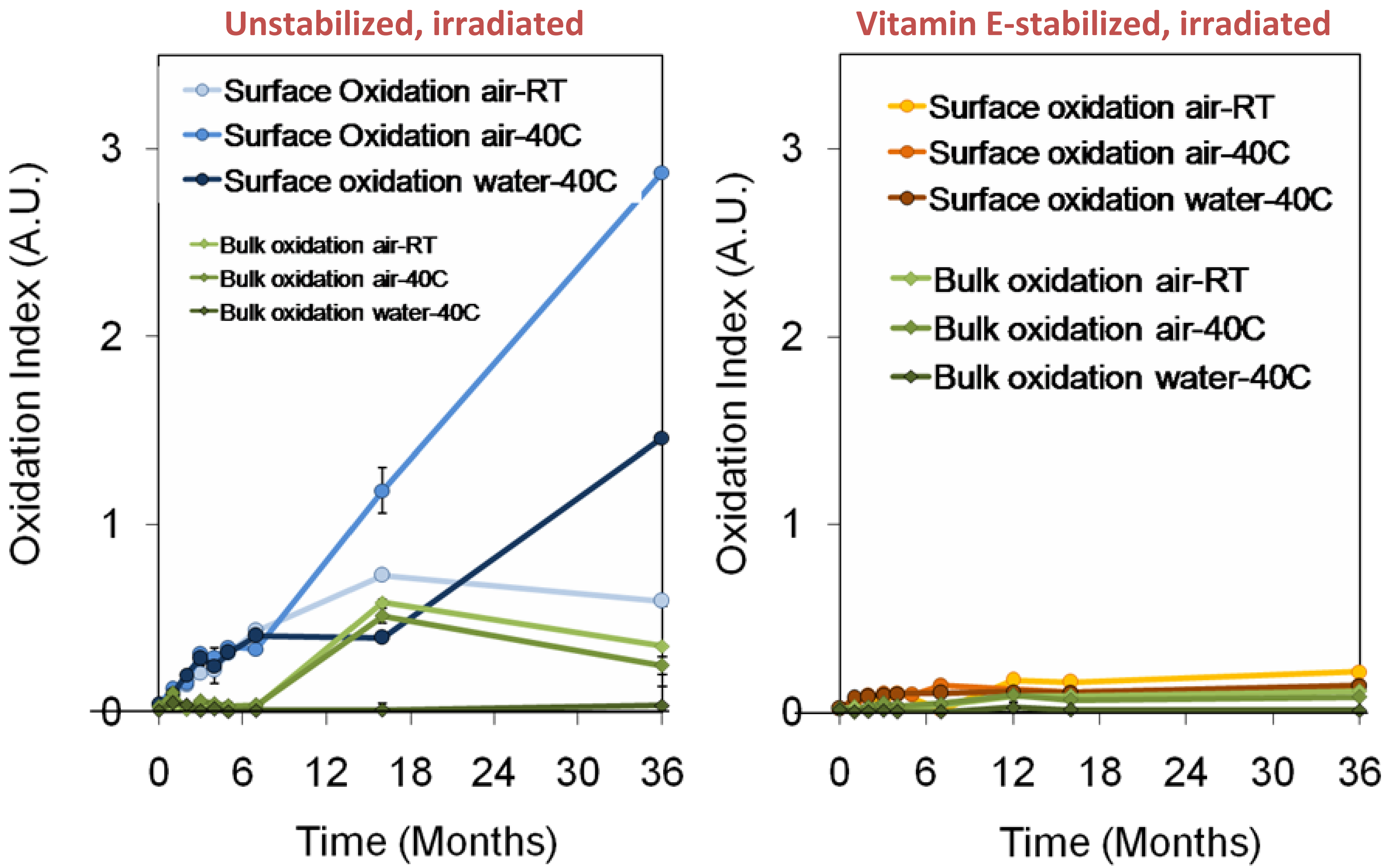


Vitamin E 28 mm

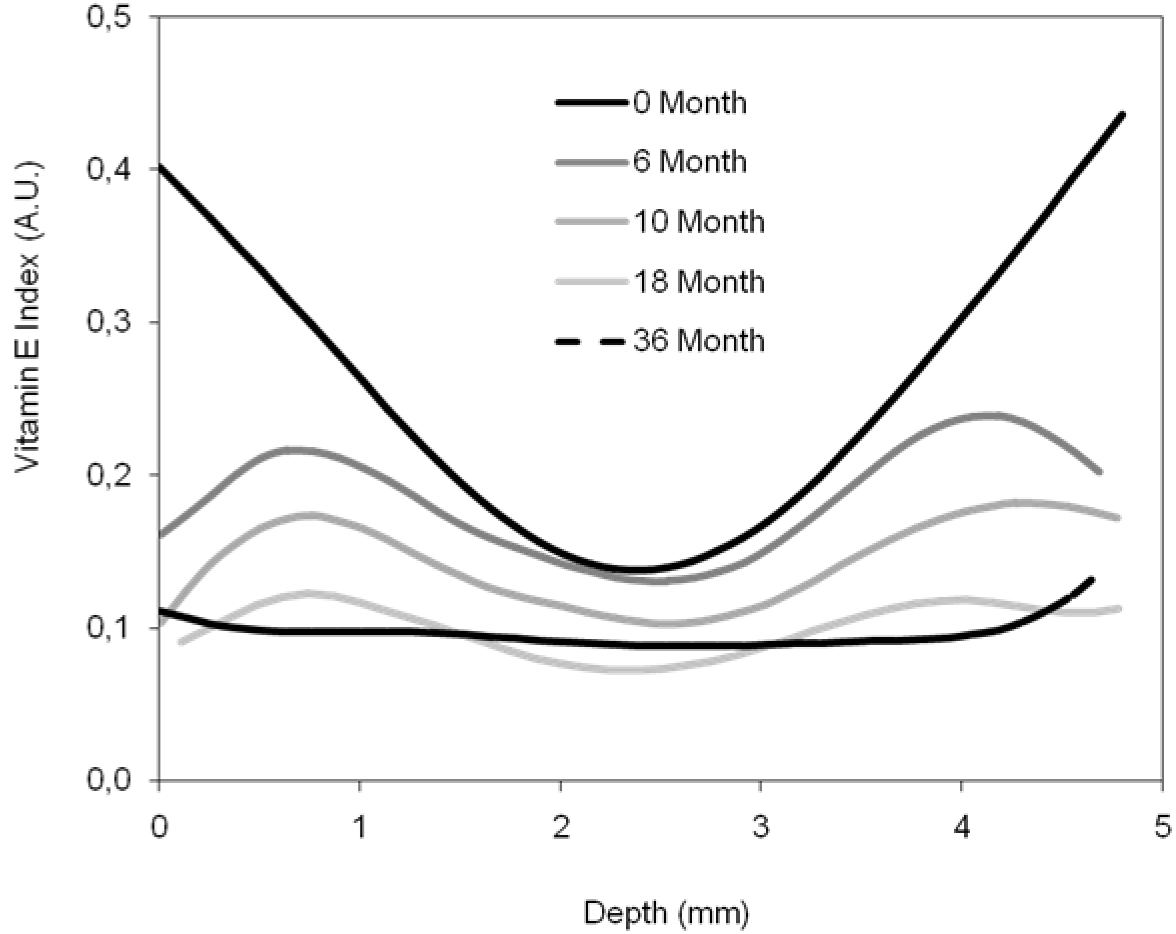


Vitamin E 40 mm

Real-time aging of vitamin E-stabilized, irradiated UHMWPE



Oral et al. The effect of alpha-tocopherol on the oxidation and free radical decay in irradiated UHMWPE. Biomaterials 27: 5580-5587 (2006)


0,5
0,4
0,3
0,2
0,1
0,0
Vitamin E Index (A.U.)
0 Month
6 Month
10 Month
18 Month
36 Month
0
1
2
3
4
5
Depth (mm)

Effect of Vitamin E on Peri-prosthetic Tissue

- Emulsified injections (up to 10mg) of vitamin E into the knee joints of rabbits showed that there was no inflammation at 12 weeks.

- Vitamin E-stabilized, irradiated UHMWPE plugs implanted into rabbits subcutaneously did not cause chronic inflammation at 12 weeks.

- Canine hip implants prepared with a high surface concentration or uniform concentration (~0.7 wt%) did not detrimentally affect bony ingrowth or chronic inflammation at 3 months.

Conclusions

- Post-irradiation diffusion stabilization of UHMWPE was used to avoid the hindrance of vitamin E in cross-linking UHMWPE.
- Diffusion was achieved by using high temperature doping followed by high temperature homogenization without dimensional stability changes and with fine control of the amount of antioxidant.
- Vitamin E-diffused, irradiated UHMWPE showed lower wear compared to conventional UHMWPE and fatigue resistance higher than irradiated and melted UHMWPE.
- Vitamin E does not appear to have detrimental effects on peri-prosthetic tissue in animal studies.